

## § 522.960

## 21 CFR Ch. I (4–1–05 Edition)

### § 522.960 Flumethasone implantation or injectable dosage forms.

#### § 522.960a Flumethasone suspension.

(a) *Chemical name.* 6 $\alpha$ ,9 $\alpha$ -Difluoro-11 $\beta$ ,17,21 - trihydroxy - 16 $\alpha$  - methylpregna - 1,4 - diene - 3,20 - dione.

(b) *Specifications.* Flumethasone suspension is sterile and each milliliter of the drug contains: 2 milligrams of flumethasone, 20 milligrams of propylene glycol, 9 milligrams of benzyl alcohol (as preservative), 8 milligrams of sodium chloride, 0.02 milligram of polysorbate-80, 0.1 milligram of citric acid, and water for injection q.s.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is recommended in the various disease states involving synovial structures (joints) of horses where excessive synovial fluid of inflammatory origin is present and where permanent structural changes do not exist. Such conditions include arthritis, carpalitis, and osselets.

(2) The drug is administered intraarticularly at a dosage level of 6 to 10 milligrams per injection. The dosage level is dependent upon the size of the involved synovial structure and the degree of severity of the condition under treatment. The dosage is limited to a single injection per week in any one synovial structure.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally and parenterally to animals during the last trimester of pregnancy may induce the first stage of parturition and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. The drug is not to be used in horses intended for slaughter for food purposes.

(4) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975. Redesignated at 44 FR 16011, Mar. 16, 1979, as amended at 61 FR 5506, Feb. 13, 1996]

#### § 522.960b Flumethasone acetate injection.

(a) *Chemical name.* 6- $\alpha$ ,9- $\alpha$ -difluoro - 16 -  $\alpha$  - methylprednisolone 21-acetate.

(b) *Specifications.* Flumethasone injection is sterile and contains per cubic

centimeter: 2 milligrams of flumethasone acetate; 20 milligrams of propylene glycol; 9 milligrams of benzyl alcohol (as preservative); 8 milligrams of sodium chloride; 1 milligram of polysorbate 80; 0.1 milligram of citric acid; water for injection q.s.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is recommended in certain acute and chronic canine dermatoses of varying etiology to help control the pruritus, irritation, and inflammation associated with these conditions.

(2) The drug is administered intramuscularly at the following recommended daily dosage:

Weight of animal in pounds	Dosage in milligrams
Up to 10 .....	1.0
10 to 25 .....	2.0
25 and over .....	4.0

Dosage should be adjusted according to the weight of the animal, the severity of the symptoms, and the response noted. Dosage by injection should not exceed 3 days of therapy. With chronic conditions intramuscular therapy may be followed by oral administration of flumethasone tablets at a daily dose of from 0.0625 to 0.25 milligram per animal.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975. Redesignated at 44 FR 16011, Mar. 16, 1979, as amended at 61 FR 5507, Feb. 13, 1996]

#### § 522.960c Flumethasone solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 0.5 milligram flumethasone.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used as follows:

(1) *Horses*—(i) *Amount.* 1.25 to 2.5 milligrams daily, intravenously, intramuscularly, or intra-articularly.

(ii) *Indications for use.* It is used for the treatment of musculoskeletal conditions due to inflammation, where permanent structural changes do not exist, e.g., bursitis, carpalitis, osselets, and myositis; and allergic states, e.g., hives, urticaria, and insect bites.

(iii) *Limitations*—(a) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(b) When a long-term therapy is used, the dose should be individually adjusted to the minimum maintenance dose. A protein-rich diet is useful in dogs and cats on long-term therapy to counteract nitrogen loss if it should occur. A small amount of potassium chloride daily in the diet will counteract excessive potassium loss if this is present.

(c) It has been demonstrated that corticosteroids, especially at high dose levels, may result in delayed wound and fracture healing.

(d) Flumethasone may be administered to animals with bacterial diseases provided appropriate antibacterial therapy is administered simultaneously.

(e) The drug is not to be used in horses intended for slaughter for food purposes.

(f) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount*. 0.0625 to 0.25 milligram daily, intravenously, intramuscularly, or subcutaneously; 0.125 to 1.0 milligram daily, intralesionally, depending on the size and location of the lesion; 0.166 to 1.0 milligram daily, intra-articularly, depending on the severity of the condition and the size of the involved joint.

(ii) *Indications for use*. It is used for the treatment of musculoskeletal conditions due to inflammation of muscles or joints and accessory structures where permanent structural changes do not exist, e.g., arthritis, osteoarthritis, disc syndrome, and myositis (in septic arthritis, appropriate antibacterial therapy should be concurrently administered); certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation; otitis externa in conjunction with topical medication; allergic states, e.g., hives, urticaria,

and insect bites; and shock and shock-like states by intravenous administration.

(iii) *Limitations*. See paragraph (c)(1)(iii) of this section.

(3) *Cats*—(i) *Amount*. 0.03125 to 0.125 milligram daily intravenously, intramuscularly, or subcutaneously.

(ii) *Indications for use*. It is used for the treatment of certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation.

(iii) *Limitations*. See paragraph (c)(1)(iii) of this section.

[44 FR 16011, Mar. 16, 1978, as amended at 61 FR 5507, Feb. 13, 1996]

#### § 522.970 Flunixin.

(a) *Specifications*. Each milliliter of solution contains flunixin meglumine equivalent to 50 milligrams (mg) flunixin.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) See No. 000061 for use as in paragraph (e) of this section.

(2) See Nos. 055529, 057561, and 059130 for use as in paragraphs (e)(1), (e)(2)(i)(A), (e)(2)(ii)(A), and (e)(2)(iii), of this section.

(3) See No. 000856 for use as in paragraph (e)(1) of this section.

(c) *Related tolerances*. See § 556.286 of this chapter.

(d) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount*. 0.5 mg per pound (lb) of body weight per day, intravenously or intramuscularly, for up to 5 days.

(ii) *Indications for use*. For alleviation of inflammation and pain associated with musculoskeletal disorders, and alleviation of visceral pain associated with colic.

(iii) *Limitations*. Not for use in horses intended for food.

(2) *Cattle*—(i) *Amount*. (A) 1.1 to 2.2 mg/kilogram (kg) (0.5 to 1.0 mg/lb) of body weight per day, as a single dose or divided into two doses administered at 12-hour intervals, intravenously, for up to 3 days.

(B) 2.2 mg/kg (1.0 mg/lb) of body weight given once by intravenous administration.